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C. R. Bard, Inc. and
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation

No. 2:15-MD-02641-DGC

**DEFENDANTS C. R. BARD, INC.'S
AND BARD PERIPHERAL
VASCULAR, INC.'S MOTION TO
AMEND AND CERTIFY THE
COURT'S NOVEMBER 22, 2017
ORDER FOR INTERLOCUTORY
APPEAL PURSUANT TO 28 U.S.C.
§ 1292(B)**

(Assigned to the Honorable David G.
Campbell)

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively
“Bard”) respectfully move this Court to amend its November 22, 2017, Summary
Judgment Order (Doc. 8872) (the “Order”) to certify it for interlocutory appeal pursuant to
28 U.S.C. § 1292(b). In support of this Motion, Bard submits the following Memorandum

of Points and Authorities:

MEMORANDUM OF POINTS AND AUTHORITIES

I. Interlocutory Appeal From the Order Is Appropriate Under 28 U.S.C. § 1292(b).

A district court may certify an order for interlocutory appeal under 28 U.S.C. § 1292(b) when the order: (1) “involves a controlling question of law” (2) “as to which there is a substantial ground for difference of opinion,” and (3) “an immediate appeal from the order may materially advance the ultimate termination of the litigation.” *Id.*; see also *In re Cement Antitrust Litig.*, 673 F.2d 1020, 1026 (9th Cir. 1982). Bard respectfully requests certification here because the Court’s Order satisfies all three prerequisites.

A. The Order Involves a Controlling Question of Law.

Under Section 1292(b), “all that must be shown in order for a question to be ‘controlling’ is that resolution of the issue on appeal could materially affect the outcome of litigation in the district court.” *In re Cement Antitrust Litig.*, 673 F.2d at 1026. “[Federal] preemption, by its very nature, lends itself to interlocutory appeals” and is “undoubtedly a controlling question of law.” *Knipe v. SmithKline Beecham*, 583 F. Supp. 2d 553, 599 (E.D. Pa. 2008) (granting interlocutory appeal under § 1292(b) on question of federal preemption of state-law claims under Food, Drug, and Cosmetic Act (“FDCA”) involving pharmaceutical product); see also, e.g., *Harris By & Through Harris v. Ford Motor Co.*, 110 F.3d 1410, 1411–12 (9th Cir. 1997) (hearing interlocutory appeal under § 1292(b) regarding whether National Traffic and Motor Vehicle Safety Act preempted state tort law); *Nutrishare, Inc. v. Connecticut Gen. Life Ins. Co.*, No. 2:13-CV-02378-JAM-AC, 2014 WL 2624981, at *4 (E.D. Cal. June 12, 2014) (certifying order for appeal on federal preemption issue); *Brown v. Hain Celestial Grp., Inc.*, No. C 11-03082 LB, 2012 WL 4364588, at *3 (N.D. Cal. Sept. 24, 2012) (same); *Deming v. First Franklin*, No. 09-5418RJB, 2010 WL 2326170, at *1 (W.D. Wash. June 7, 2010) (same); *Helman v. Alcoa Glob. Fasteners Inc.*, No. CV09-1353 SVW (FFMX), 2009 WL 2058541, at **5–7 (C.D. Cal. June 16, 2009) (same); *Pac. Merch. Shipping Ass’n v.*

1 *Goldstene*, No. 2:09-CV-01151MCEEFB, 2009 WL 2777778, at *8 (E.D. Cal. Aug. 28,
2 2009) (same); *Wells Fargo Bank v. Bourns, Inc.*, 860 F. Supp. 709, 717 (N.D. Cal. 1994)
3 (same).

4 If the Ninth Circuit were to disagree with this Court’s conclusion that Plaintiff’s
5 claims are not expressly preempted by the Medical Device Amendments of 1976 (the
6 “MDA”), 21 U.S.C. § 360 *et seq.*, nor impliedly preempted by the MDA under the
7 Supreme Court’s conflict preemption principles, then Plaintiffs’ state-law claims could
8 not go forward. *Nutrishare, Inc.*, 2014 WL 2624981, at *3 (citing *In re Cement Antitrust*
9 *Litig.*, 673 F.2d at 1026) (“Whether CIGNA can even bring its state law claims is certainly
10 a controlling question of law. If the Ninth Circuit finds the claims preempted, the
11 decision would ‘materially affect the outcome of the litigation.’ Such a finding would
12 also materially advance the ultimate resolution of the litigation, as it could eliminate the
13 causes of action and obviate any need for the Court to address them.”). The outcome of
14 this litigation will be significantly and materially affected if the question of federal
15 preemption is decided in Bard’s favor. Therefore, the Order involves a controlling
16 question of law appropriate for interlocutory appeal.¹

17 **B. Substantial Grounds For Difference of Opinion Exist Regarding the**
18 **Question of Law Presented.**

19 To be certified under § 1292(b), this Court “must examine to what extent the
20 controlling law is unclear.” *Couch v. Telescope Inc.*, 611 F.3d 629, 633 (9th Cir. 2010).
21 “Courts traditionally will find that a substantial ground for difference of opinion exists
22 where the circuits are in dispute on the question and the court of appeals of the circuit has
23 not spoken on the point . . . or if novel and difficult questions of first impression are
24 presented.” *Id.* (citations and quotations omitted). While “the mere presence of a
25 disputed issue that is a question of first impression, standing alone, is insufficient,” *id.* at
26 634, “[a] substantial ground for difference of opinion exists . . . when novel legal issues

27
28 ¹ “Furthermore, because this is a ‘pure legal question’ involving no factual issues, an
interlocutory appeal is especially appropriate.” *Helman*, 2009 WL 2058541, at *5.

1 are presented[] on which fair-minded jurists might reach contradictory conclusions,” even
 2 if “there are no cases directly conflicting with the district court’s construction of the law.”
 3 *Reese v. BP Expl. (Alaska) Inc.*, 643 F.3d 681, 688 (9th Cir. 2011).

4 The controlling law on federal preemption of 510(k)-cleared devices is unclear. As
 5 Justice Neil Gorsuch recently commented before his elevation to the Supreme Court,
 6 “[t]he Supreme Court has issued a number of opinions that embody ‘divergent views’
 7 about the proper role of the MDA’s preemption provision, a fact that has yielded
 8 considerable ‘uncertainty’ among the lower courts.” *Caplinger v. Medtronic, Inc.*, 784
 9 F.3d 1335, 1337 (10th Cir. 2015). For preemption to exist, “a device must undergo the
 10 premarket approval process—or, the [Supreme] Court suggested, perhaps something like
 11 it.” *Id.* at 1339. While “the Court acknowledged the possibility that ‘general’ federal
 12 requirements might sometimes preempt state requirements,” the Supreme Court’s
 13 preemption cases provide little guidance regarding “when and what kinds of ‘general
 14 requirements’ have preemptive effect, or what sort of device-specific regulations beyond
 15 the premarket approval process might bear that same power.” *Id.* Because of this
 16 uncertainty in the controlling law, Justice Gorsuch suggested that “perhaps some of those
 17 rules warrant revisiting and reconciliation.” *Id.* at 1340. This case offers the opportunity
 18 to do just that.

19 Moreover, the Order involves novel and difficult questions of first impression “on
 20 which fair-minded jurists might reach contradictory conclusions.” *Reese*, 643 F.3d at 688.
 21 No court, including the Ninth Circuit, has addressed preemption where a 510(k)-cleared
 22 device has the kind of developed factual record, special controls, device-specific
 23 Guidance, history of down classification, and extensive regulatory review associated with
 24 Bard’s IVC filters. As this Court recognized, however, before the opinion was vacated,
 25 the Ninth Circuit in *Degelmann* held an FDA Guidance “document containing the special
 26 controls for lens solution” to be a specific requirement that preempted the plaintiffs’ state-
 27 law claims. *Degelmann v. Advanced Med. Optics, Inc.*, 659 F.3d 835, 841-42 (9th Cir.
 28 2011), *vacated*, 699 F.3d 1103 (9th Cir. 2012). This was true even though the Ninth

Circuit recognized that the Guidance document explicitly permitted alternative approaches to satisfying the requirements. *Id.* at 842; *see also Papike v. Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997) (device-specific regulation preemptive). Therefore, “[i]t is not inconceivable that the Ninth Circuit could conclude that this Court applied an overly” restrictive view of federal preemption when it denied Defendants’ motion for summary judgment. *Cal Pure Pistachios, Inc. v. Primex Farms, LLC*, No. CV 09-7874-GW(RCX), 2010 WL 11523707, at *2 (C.D. Cal. Apr. 29, 2010) (granting certification on issue of whether Lanham Act, which provided foundation for Plaintiff’s state-law claims, applied).

Although this Court found *Papike* and *Degelmann* to be distinguishable, Bard respectfully submits that substantial grounds for difference of opinion exist because the fair-minded jurists of the Ninth Circuit might reach a different conclusion. *See, e.g., Reese*, 643 F.3d at 688; *Knipe*, 583 F. Supp. 2d at 600 (finding substantial grounds for difference of opinion where “preemption decision involve[d] a rather novel question of law, which the Third Circuit ha[d] not yet had the opportunity to address,” especially where particular question at issue generated but a single judicial opinion finding preemption based on “highly distinguishable facts”).

This case will provide an opportunity for the Ninth Circuit to revisit its vacated reasoning in *Degelmann* on the novel issue of the preemptive effect of “special controls” such as a Guidance document, as well as to address whether the FDA can and has imposed the sort of device-specific requirements beyond regulations and “beyond the premarket approval process [that] might bear that same [preemptive] power.” *Caplinger*, 784 F.3d at 1339. That is, whether FDA’s regulatory review of Bard’s IVC Filters approached the “something like” premarket approval review that is entitled to “preemptive effect.” *Id.*

Accordingly, there exists substantial grounds for difference of opinion regarding the difficult questions of whether Plaintiffs’ state law claims are expressly or impliedly preempted. Thus, these issues should be fully presented to, and decided by, the Ninth Circuit.

C. Immediate Appeal From the Order Will Materially Advance the Ultimate Termination of This Litigation.

A district court should certify an order for immediate appeal when there is “a highly debatable question that is easily separated from the rest of the case, that offers an opportunity to terminate the litigation completely, and that may spare the parties the burden of a trial that is expensive for them even if not for the judicial system.” *Helman*, 2009 WL 2058541, at *6 (quoting Wright, Miller, & Cooper, Federal Practice and Procedure Jurisdiction 2D § 3930, at 436 (1996)). The question of whether Plaintiffs’ state law claims are preempted (expressly or impliedly) is easily separated from the rest of the case as evidenced by the fact that this Court ordered dispositive briefing on the issue separate from the dispositive briefing specific to the individual bellwether cases.

Moreover, allowing an interlocutory appeal on this question might “avoid protracted and expensive litigation,” *In re Cement Antitrust Litig.*, 673 F.2d at 1026, because a determination that federal preemption does apply would eliminate Plaintiffs’ state law claims “and obviate any need for the Court to address them.” *Nutrishare, Inc.*, 2014 WL 2624981, at *3; *Brown*, 2012 WL 4364588, at *4 (“[I]nterlocutory appeal could materially advance termination of the litigation” where “successful appeal” on preemption could “result in dismissal of all of Plaintiff’s claims”). Indeed, such a determination could completely terminate the litigation of the 3,000 personal injury cases remaining in this MDL. *See, e.g., In re Fosamax Prod. Liab. Litig.*, No. 06 CIV. 9455 JFK, 2011 WL 2566074, at *10 (S.D.N.Y. June 29, 2011) (certifying order where immediate appeal “will materially advance termination of this [bellwether] case, as well as the *Fosamax MDL*”); *see also In re Michaels Stores, Inc., Wage & Hour Employment Practices Litig.*, No. MDL 14-2531-GW(AGRX), 2014 WL 12604981, at *3 (C.D. Cal. Sept. 15, 2014).

Furthermore, “[c]ertification is particularly appropriate in the context of MDL proceedings,” as a “prompt appeal now will allow a single court to review the [dispositive] issue presented, thus ‘enhancing the likelihood of achieving the coordination benefits sought by 28 U.S.C. § 1407 (the ‘just and efficient conduct’ of multidistrict

actions), as the circuit of the § 1407 transferee court can give the issues a unified treatment.” *In re Cintas Corp. Overtime Pay Arbitration Litig.*, No. M06-CV-01781-SBA, 2007 WL 1302496, at *2 (N.D. Cal. May 2, 2007) (quoting *Hill v. Henderson*, 195 F.3d 671, 678 (D.C. Cir. 1999)).

Denying certification “would needlessly multiply this litigation, at extraordinary expense to the parties and the court system” by requiring Bard to appeal 3,000 “separate cases in 11 courts of appeals simply to obtain review of the MDL Court’s single order covering each of the consolidated cases.” *Id.* at *3. Such a denial “would undermine the very purposes of the MDL proceeding that brought the cases together before this Court. However, if this Court certifies the order for interlocutory appeal and the Ninth Circuit accepts the appeal, the Ninth Circuit’s ruling will be law of the case in these MDL proceedings.” *Id.* (following “the favored MDL practice and certif[y]ing its order for interlocutory appeal” in MDL litigation); *Hill*, 195 F.3d at 677 (“[T]he practice has favored certification by the transferee court of potentially outcome determinative rulings for immediate, consolidated appeal under 28 U.S.C. § 1292(b).”); *In re Korean Air Lines Disaster of September 1, 1983*, 829 F.2d 1171, 1180 (D.C. Cir. 1987) (en banc) (Ginsburg, J., concurring) (“A series of inconsistent appellate judgments is not a desirable outcome, however, particularly since the result in some cases might be to require renewed pretrial or trial proceedings. This whole course of case development, starting with divergent paths of appeal and ending with either conflicting or duplicative results, would clearly frustrate the primary goals of section 1407 (a) ‘to promote the just and efficient conduct’ of multi-district actions.”), *aff’d sub nom. Chan v. Korean Air Lines, Ltd.*, 490 U.S. 122 (1989).

Therefore, the Order satisfies the third requirement under 28 U.S.C. § 1292(b).

II. Interlocutory Appeal Will Not Stay the Proceedings and Will Not Delay the Litigation.

To be clear, Bard does not seek a stay of the underlying proceedings, nor is one required under 28 U.S.C. § 1292(b). *Id.* (“[A]pplication for an appeal hereunder shall not

1 stay proceedings in the district court unless the district judge or the Court of Appeals or a
 2 judge thereof shall so order.”); *see also Plotkin v. Pac. Tel. & Tel. Co.*, 688 F.2d 1291,
 3 1293 (9th Cir. 1982) (citations omitted) (“[A]n appeal from an interlocutory order does
 4 not stay the proceedings, as it is firmly established that an appeal from an interlocutory
 5 order does not divest the trial court of jurisdiction to continue with other phases of the
 6 case.”). Furthermore, Bard’s counsel does not anticipate that an interlocutory appeal
 7 would delay or otherwise impede this Court’s ability to conduct the bellwether trials or
 8 otherwise manage the MDL pending the outcome of such an appeal.

9 **III. Conclusion.**

10 For these reasons, Bard respectfully requests that this Court amend and certify its
 11 November 22, 2017, Summary Judgment Order (Doc. 8872) for interlocutory appeal
 12 pursuant to 28 U.S.C. § 1292(b) by including the following language:

13 The Court is of the opinion that this Order involves a controlling question of
 14 law as to which there is substantial ground for difference of opinion and that
 15 an immediate appeal from this Order as authorized by 28 U.S.C. § 1292(b)
 may materially advance the ultimate termination of this litigation.

16 Respectfully submitted this 8th day of December, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on December 8, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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